

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

MEADE, Christopher J.M. et al.

Examiner: Eric Olson

Serial No.: 10/614,365

Group Art Unit: 1623

Filed: June 7, 2003

Confirmation No.: 7867

Title: PHARMACEUTICAL COMPOSITIONS BASED ON ANTICHOLINERGICS
AND PDE-IV INHIBITORS

REPLY BRIEF UNDER 37 C.F.R. §41.41

Mail Stop: Appeal Brief

Commissioner for Patents

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SIR:

This Reply Brief is submitted under 37 C.F.R. §41.41 in response to the Examiner's Answer, mailed October 29, 2007. Appellants maintain their reliance upon their Brief filed July 23, 2007. The following points are made for emphasis or clarification of points made in the Brief in light of the comments thereon in the Examiner's Answer and/or are made in response to new points of argument raised in the Examiner's Answer.

- (1) The Examiner's Answer alleges (page 6, third paragraph; and page 9, second full paragraph) that "one of ordinary skill in the art would have been motivated to prepare the composition using the anticholinergic 1 of Meissner et al. in place of the anticholinergics of Knowles et al. because this compound is also an anticholinergic." Appellants respectfully disagree that one of ordinary skill in the art would be motivated to replace the anticholinergics of Knowles with any other

anticholinergic compound (such as that of Meissner) simply because it is referred to generally as an anticholinergic. Knowles uses the term “an anticholinergic” on pages 1-2 of its disclosure but defines this term by its discussion at page 4, line 28, to page 6, line 4. Knowles states at page 4, line 28, that “the anticholinergic agents of this invention are ...” before it goes on to describe the particular receptor effects required for its purposes. Knowles thus defines the term in this context and not merely as a preference. The “anticholinergic” term in Knowles is limited by this description since no other meaning is described in Knowles for this term. Thus, the teaching from Knowles is to use an anticholinergic as described and exemplified at page 4, line 28, to page 6, line 4. Knowles does not teach the use of other agents – which others may describe as anticholinergics – but which do not meet the above-cited description given in Knowles. There is no basis on the record to reasonably conclude that the “new anticholinergics” described by Meissner (see col. 1, lines 11-30) are of the type of anticholinergic taught to be useful for the purposes of Knowles’ invention. Appellants urge that obviousness cannot simply be based on the fact that Knowles and Meissner both use the term “anticholinergic” and an assumption made that these terms were used in the same way in each reference. The terms must be viewed in the context of each reference as a whole. For the reasons discussed at pages 7-9 of the Brief, appellants urge that, when the reference teachings are considered as a whole, there is no suggestion to one of ordinary skill in the art that an anticholinergic of Meissner

could be interchanged for an anticholinergic of Knowles with the expectation of compositions having the same or similar properties. Particular emphasis is directed to the fact that Meissner refers to compounds of the type disclosed as anticholinergics in Knowles – i.e., benzilic acid esters – in its Background section (col. 1, line 33, to col. 2, line 26) and teaches that such compounds are deficient in meeting the requirements desired for the Meissner invention. Thus, Meissner's invention was purposefully directed to structurally distinct compounds with distinct properties. Meissner teaches away from the use of the benzilic acid esters which are the preferred “anticholinergics” of Knowles. This provides a clear teaching to one of ordinary skill in the art that the Meissner compounds would not be expected to exhibit the same or similar properties as the compounds considered by Knowles to be anticholinergics. Thus, the references direct one of ordinary skill in the art away from the combination necessary to arrive at the claimed invention on appeal. In this context, appellants also refer to the comments in the Examiner's Answer (paragraph bridging pages 9-10) regarding the specific types of M1/M2 receptors. Appellants arguments on this point (page 8, first paragraph, of the Brief) did not allege that Knowles absolutely required the specific receptor antagonism. Appellants argument was that these teachings also must be considered when viewing the reference as a whole and further support that there is no reasonable expectation that the anticholinergics of Meissner would have the same or similar properties as the anticholinergics of Knowles and thus could be

used interchangeably.

- (2) The Examiner's Answer alleges (page 6, third paragraph; and sentence bridging pages 7-8) that "one of ordinary skill in the art would have been motivated to prepare the composition using the anticholinergic 1 of Meissner et al. in place of the anticholinergics of Knowles et al. because this compound .. is structurally similar to the compounds of Knowles et al." However, the part of the Examiner's Answer (pages 8-11) which responds to Appellants' Brief provides no rebuttal or disagreement with appellants' arguments (pages 5-7 of the Brief) pointing out the significant structural distinctions of the Meissner compounds and appellants' compound 1 from the compounds disclosed as anticholinergics in Knowles. Appellants thus urge that the structural similarity arguments previously made in the Final Office action to support the obviousness rejection are not supported on the record and the Examiner appears to have dropped reliance on such arguments.
- (3) The Examiner's Answer alleges (page 6, third paragraph; and page 9, first full paragraph) that "one of ordinary skill in the art would have been motivated to prepare the composition using the anticholinergic 1 of Meissner et al. in place of the anticholinergics of Knowles et al. because this compound ... is useful for treating the same condition (i.e., obstructive pulmonary condition)." Appellants respectfully submit that Knowles and Meissner do not teach the use of their

respective “anticholinergics” for the same use. Knowles teaches that its anticholinergics are useful when in combination with PDE4 inhibitors to treat pulmonary diseases, such as COPD. Meissner teaches the use of its distinct anticholinergics – absent combination with PDE4 inhibitors – to treat asthma or COPD. There is no suggestion or reasonable expectation from the record that the distinct anticholinergics of Meissner would be useful for treating COPD when used in combination with PDE4 inhibitors.

- (4) The Examiner’s Answer alleges (page 10, first full paragraph) that Meissner’s teaching that its distinct anticholinergics are superior to benzilic acid esters, such as those of Knowles, supports using them in place of the anticholinergics of Knowles, rather than teaches away from such interchange. Appellants respectfully disagree. As pointed out above, the purposes of Knowles and Meissner are different. The purpose of Knowles is to provide compounds which are useful to treat pulmonary diseases when used in combination with PDE4 inhibitors. Meissner’s teachings that its anticholinergics are superior to other anticholinergics to treat asthma or COPD does not suggest that they would necessarily be superior (or useful at all) when combined with PDE4 inhibitors.

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For the above reasons and the reasons set forth in Appellants' Brief, it is submitted that the decision of the Examiner finally rejecting claims 1, 2, 4, 5, 7-11, 13, 19-38, 43 and 44, on appeal, is in error and should be reversed.

Respectfully submitted,

/John A. Sopp/

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